510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k112408

B. Purpose for Submission:
New 510(k) for the addition of an Ion Selective Electrode Module for the previously cleared Poly-Chem 90 analyzer (k090703)

C. Measurand:
Sodium, Potassium, Chloride

D. Type of Test:
Quantitative Ion Selective Electrodes (ISE)

E. Applicant:
POLYMEDCO, INC.

F. Proprietary and Established Names:
POLY-CHEM 90 ISE MODULE

G. Regulatory Information:

1. Regulation section:
   21CFR Sec.- 862.1600-Potassium test system.
   21CFR Sec.- 862.1170-Chloride test system.
   21CFR Sec.- 862.1665-Sodium test system.

2. Classification:
   II

3. Product code:
   CEM - Electrode, Ion Specific, Potassium
   CGZ - Electrode, Ion-Specific, Chloride
   JGS - Electrode, Ion Specific, Sodium

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See Indication(s) for use below
2. Indication(s) for use:

   The Poly-Chem 90 ISE Module is for the quantitative in vitro measurement of

sodium, potassium, and chloride in human serum on the Poly-Chem 90 clinical chemistry analyzer.

Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

3. Special conditions for use statement(s):
   Prescription use
4. Special instrument requirements:
   POLY-CHEM 90 analyzer (k090703) and ISE module

I. Device Description:

The POLY-CHEM 90 ISE module is integrated on the Poly-Chem 90, a bench-top fully automated random access clinical analyzer. The analyzer has the capacity to perform up to 90 tests per hour plus ISEs, and offers primary tube sampling, on-board sample dilution and a cooled reagent compartment.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Randox RX Daytona ISE Module
2. Predicate 510(k) number(s):
   k024014
3. Comparison with predicate:

Similarities and Differences ISE Module		
Item	Poly-Chem 90 ISE Module	RX Daytona ISE Module
Intended Use /Indications for Use	For the quantitative in vitro measurement of the level of sodium, potassium, and chloride. Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied	Same

Similarities and Differences ISE Module		
Item	Poly-Chem 90 ISE Module	RX Daytona ISE Module
	by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.	
Analyzer	Poly-Chem 90 analyzer.	RX Daytona analyzer.
Sample type	Serum	Serum, plasma, urine
Methodology	Ion selective electrode	Same
Calibration	Medica Calibrator A and Calibrator B	Same
Analyzer	Poly-Chem 90	RX Daytona

K. Standard/Guidance Document Referenced (if applicable):

- CLSI - Evaluation of Precision Performance of Clinical Chemistry Devices - EP05-A2
- CLSI - Evaluation of the Linearity of Quantitative Analytical Methods - EP06-A
- CLSI - Protocols for Determination of Limits of Detection and Limits of Quantitation - EP17-A
- ISO 14971:2007, Medical devices - Application of risk management to medical devices.

L. Test Principle:

ISE measurements are based on the potentiometric Nernst Equation principle. The measured potential difference between the reference electrode and the ion specific electrodes is proportional to the logarithm of the concentration of the measured ions.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>
   a. Precision/Reproducibility:
   Precision studies were performed at three levels of each test, on two separate instruments, over 10 days. Serum samples were tested in duplicate twice a day.

				Within run		Between run	
	Sample	Instrument	Mean (mmol/L)	SD	CV	SD	CV

				Within run		Between run	
	Sample	Instrument	Mean (mmol/L)	SD	CV	SD	CV
Sodium	1	1	83.54	0.222	0.27	0.781	0.94
		2	82.91	0.101	0.12	0.589	0.71
	2	1	139.05	0.254	0.18	0.783	0.56
		2	139.70	0.160	0.11	0.646	0.46
	3	1	172.03	0.285	0.17	0.768	0.45
		2	172.95	0.099	0.06	0.481	0.28

				Within run		Between run	
	Sample	Instrument	Mean (mmol/L)	SD	CV	SD	CV
Potassium	1	1	2.43	0.008	0.33	0.026	1.08
		2	2.41	0.007	0.29	0.022	0.90
	2	1	3.91	0.007	0.18	0.019	0.49
		2	3.89	0.007	0.17	0.017	0.43
	3	1	7.3	0.012	0.16	0.046	0.63
		2	7.3	0.010	0.14	0.049	0.68
Chloride	1	1	54.4	0.29	0.54	0.66	1.20
		2	53.8	0.17	0.32	0.53	0.98
	2	1	101.0	0.15	0.14	0.35	0.34
		2	101.0	0.08	0.08	0.37	0.36
	3	1	134.0	0.15	0.11	0.45	0.34
		2	133.8	0.13	0.10	0.44	0.33

b. Linearity/assay reportable range:

Reportable range based on linearity and detection limit below:
33.5 – 191.6 mmol/L (Na)
1.09 – 9.98 mmol/L (K)
41.0 – 169.8 mmol/L (Cl)

Dilution series for the assay was prepared by mixing human serum with human serum containing the analyte to several levels of the test. The diluted samples were tested in triplicate on the Poly-Chem 90 analyzer.

The mean of the measured concentration at each level was compared with the expected concentration based on the dilution level and the linear fit was assessed. The linearity claim is based on a percent deviation of < 10% through the linear range.

	Range (mmol/L)	**Slope (95% CI)**	**Intercept (95% CI)**	**r^2**
Sodium	30.4 – 191.6	0.99 (0.97 to 1.00)	0.09 (-1.92 to 2.11)	0.9989
Potassium	1.09 – 9.98	0.98 (0.98 to 0.99)	0.17 (0.13 to 0.21)	0.9998
Chloride	31.3 – 169.8	1.02 (1.00 to 1.04)	-5.35 (-7.62 to -3.07)	0.9989

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The calibrators, electrodes, and wash buffer used with the Poly-Chem 90 ISE are cleared under k000926

c. *Detection limit:*

The below limits of detecting was established according to CLSI - Protocols for Determination of Limits of Detection and Limits of Quantitation - EP17-A.

Test	**Limit of Blank**	**Limit of Detection**	**Limit of Quantitation (10% CV)**
Sodium	32.4 mmol/L	33.5 mmol/L	33.5 mmol/L
Potassium	0.35 mmol/L	0.393 mmol/L	0.5 mmol/L
Chloride	40.2 mmol/L	41.0 mmol/L	41.0 mmol/L

d. *Analytical specificity:*

Serum samples containing the analyte at three levels of the test were spiked with the potentially interfering substance—hemoglobin, bilirubin, and triglyceride—to several concentrations. Samples were then run in triplicate using the Poly-Chem 90 test. The recovery of the test at each concentration of interferent was calculated by comparing the mean result of testing with no interferent to the mean result at each level tested. Acceptable recovery at each level was 90 – 110%.

Test	**Hemoglobin**	**Bilirubin**	**Triglyceride**
Sodium	800 mg/dL	7.5 mg/dL	549 mg/dL
Potassium	800 mg/dL	25 mg/dL	663 mg/dL
Chloride	800 mg/dL	25 mg/dL	549 mg/dL

f. *Assay cut-off:*
Not Applicable

2. Comparison studies:
   a. Method comparison with predicate device:

   Patient serum samples (some adjusted) at several levels of the test were run on the RX Daytona instrument and the Poly-Chem 90. Results obtained from each instrument were compared using Passing-Bablok and Bland Altman analysis. Results are summarized in the table below:

Test	n	Range of samples	Slope (95% CI)	Intercept (95% CI)	r
Sodium	63	56.0 – 189.0	1.04 (1.00 to 1.08)	-5.06 (-11.47 to -0.30)	0.9929
Potassium	74	1.39 – 9.13	0.99 (0.97 to 1.01)	0.02 (-0.04 to 0.11)	0.9982
Chloride	74	49.0 – 166.0	1.01 (1.00 to 1.03)	-1.64 (-2.91 to -0.10)	0.9985

   b. Matrix comparison:
   Not Applicable

3. Clinical studies:
   a. Clinical Sensitivity:
   Not Applicable
   b. Clinical specificity:
   Not Applicable
   c. Other clinical supportive data (when a. and b. are not applicable):
   Not Applicable

4. Clinical cut-off:
   Not Applicable

5. Expected values/Reference range*:
   Sodium (serum) 136 – 146 mmol/L
   Potassium (serum) 3.5 – 5.1 mmol/L
   Chloride (serum) 97 – 107 mmol/L

   * Todd-Sanford, clinical Diagnosis by Laboratory Methods, (16th edition) W.B. Saunders Co., Philadelphia , P.A. 144-148.

N. Instrument Name:

POLY-CHEM 90 analyzer with ISE module

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:

Yes __X__ or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

Yes _____ or No __X__

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X_____ or No _____

3. Specimen Identification:

   Manual or barcode entry with optional barcode reader

4. Specimen Sampling and Handling:

   Removable tray with sample tube holder on a turntable. On-board sampling dilution capability

5. Calibration:

   ISE (reference electrode)

6. Quality Control:

   Use of quality control materials are recommended for daily runs.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not Applicable

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.